

03-08-04

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

RICH, Ivan N.

Serial No.: **10/645,077**

Filed: **August 21, 2003**

For: **HIGH-THROUGHPUT ASSAY OF HEMATOPOIETIC STEM AND
PROGENITOR CELL PROLIFERATION**

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Information Disclosure Statement
Form PTO 1449
55 References
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Womble Carlyle Sandridge & Rice, PLLC
P.O. Box 7037
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(404) 872-7000 (Telephone)
(404) 888-7490 (Facsimile)
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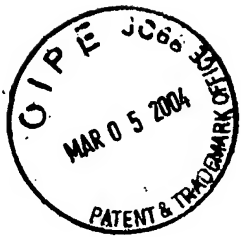
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 RICH) Docket No.: **R103 1031.1**
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 AND PROGENITOR CELL PROLIFERATION

INFORMATION DISCLOSURE STATEMENT

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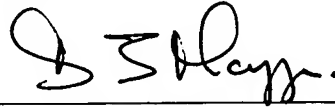
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It is respectfully requested that the Examiner initial and return copies of the enclosed PTO-1449 and to indicate in the official file wrapper of the above-identified patent application that each item of the cited information has been considered.

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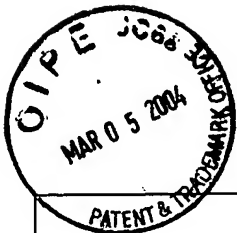
Date: 3/5/2004



David J. Hayzer, Ph.D., J.D.
Attorney for Applicant
Reg# 43,329

Womble Carlyle Sandridge & Rice, PLLC
P.O. Box 7037
Atlanta, GA 30357-0037
(404) 962-7529 (Telephone)
(404) 870-2413 (Facsimile)
Docket No.: **R103 1030.1**

ATLANTA 391789v1



AForm PTO-1449

Attorney Docket No.
R103 1031.1Serial No.
10/645,077

INFORMATION DISCLOSURE CITATION

*(Use several sheets if necessary)*Applicant
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Group

U.S. PATENT DOCUMENTS

Examiner Initials	Item	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	L	WP 92/13063	8/1992	PCT			X	

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, etc.)*

	M	"Circannual Variations Of Circadian Periodicity In Murine Colony-Forming Cells"; Aardal, Nils-Petter, Experimental Hematology, 12:61-67 (1984)
	N	"Circadian Variations in Mouse Bone Marrow"; Aardal, N.P. & Laerum, O.D., Experimental Hematology, Vol. 11, No. 9, pp. 792-801 (1983)
	O	"Cyclic Hematopoiesis in Dogs: Studies of Erythroid Burst-forming Cells Confirm an Early Stem Cell Defect"; Abkowitz, Janis L., Holly, Richard D., Hammond, William P. IV, Experimental Hematology, 16:941-945 (1988)

P	"Hematopoietic Effects of Benzene Inhalation Assessed by Long-term Bone Marrow Culture"; Abraham, Nadar G., Environmental Health Perspectives, Vol. 104, Supplement 6, pp. 1277-82 (1996)
Q	"Circadian cell cycle variations of erythro- and myelopoiesis in humans"; Abrahamsen, JF, Smaaland, R, Sothorn, RB, Laerum OD, European Journal of Haematology, Vol. 58, pp. 333-45 (1997)
R	"Circadian and seasonal variations of hematopoiesis in cord blood"; Baudoux, E., et al, Bone Marrow Transplantation, Supplement 1, S12, p. 22 (1998)
S	"Toxicity on Human Hemopoietic Progenitors of 2'-2'-Difluoro-2'-Deoxycytidine (Gemcitabine)"; Botta, Marco, et al, Anticancer Research, Vol. 18, pp. 1037-42 (1998)
T	"Measurement of the ADP:ATP ratio in human leukaemic cell lines can be used as an indicator of cell viability, necrosis and apoptosis"; Bradbury, D.A., Simmons, T.D., Slater, K.J., Crouch, S.P.M., Journal of Immunological Methods 240, pp. 79-92 (2000)
U	"The Growth Of Mouse Bone Marrow Cells <i>In Vitro</i> "; Bradley, T.R., Metcalf, D, Aust. J. Experimental Biological Medical Science, 44, pp. 287-300 (1966)
V	"Cyclic oscillations of neutrophils, monocytes, and CD8-positive lymphocytes in a healthy subject"; Carulli, Giovanni, et al, Haematologica, Vol. 85(4), pp. 447-48 (2000)
W	"Azidothymidine and interferon- α in vitro effects on hemotopoiesis: Protective in vitro activity of IL-1 and GM-CSF"; Castello, G, et al, Experimental Hematology 23, pp. 1367-71 (1995)
X	"Hematotoxicity of 5-Fluorouracil-Leucovorin in a Setting of Adjuvant Chemotherapy"; Cerruti, Alessandro, et al, Anticancer Research 14, pp. 2163-66 (1994)
Y	"Chemopreventive Agent Resveratrol, a Natural Product Derived From Grapes, Triggers CD95 Signaling-Dependent Apoptosis in Human Tumor Cells"; Clement, M., et al, Blood, Vol. 92, No. 3, pp. 996-1002 (1998)
Z	"Idarubicinol myelotoxicity: a comparison of in vitro data with clinical outcome in patients treated with high-dose idarubicin"; Corsini, C., et al, British Journal of Cancer, 82(3), pp. 524-528 (2000)
AA	"The use of ATP bioluminescence as a measure of cell proliferation and cytotoxicity"; Crouch, S.P.M., et al, Journal of Immunological Methods, 160, pp. 81-88 (1993)
BB	"Experimental basis for increasing the therapeutic index of carboplatin in brain tumor therapy by pretreatment with WR compounds"; Dox, F., et al, Cancer Chemother Pharmacol, 28, pp. 308-310 (1991)
CC	"Benzene-Induced Hematotoxicity and Bone Marrow Compensation in B6C371 Mice"; Farris, Georgia M., et al, Fundamental and Applied Toxicology 36, pp. 119-29 (1997)
DD	"Hematotoxicity on human bone marrow- and umbilical cord blood-derived progenitor cells and in vitro therapeutic index of methoxymorpholinylidoxorubicin and its metabolites"; Ghielmini, M., et al, Cancer Chemother Pharmacol 42, pp. 235-40 (1998)
EE	" <i>In vitro</i> schedule-dependency of myelotoxicity and cytotoxicity of Ecteinascidin 743 (ET-743)"; Ghielmini, M., et al, Annals of Oncology 9, pp. 989-93 (1998)

FF	"Differential toxicity of anticancer drugs on late (GM-CFC) and early (LTC-IC) hemopoietic progenitors <i>in vitro</i> "; Ghielmini, M., et al, Cell Biology and Toxicology 15, pp. 395-404 (1999)
GG	"Inhibition of CFU-E/BFU-E by 3'-Azido-3'-deoxythymidine, Chlorpropamide, and Protoporphirin IX Zinc (II): A Comparison between Direct Exposure of Progenitor Cells and Long-Term Exposure of Bone Marrow Cultures"; Gribaldo, L., et al, Toxicological Sciences 58, pp. 96-101 (2000)
HH	"Hemotopoietic dynamics in grey collies"; Haurie, Caroline, et al, Experimental Hematology 27, pp. 1139-48 (1999)
II	"The Organization of Hemopoietic Tissue as Inferred from the Effects of 5-Fluorouracil"; Hodgson, G.S., Bradley, T.R. & Radley, J.M., Experimental Hematology, Vol. 10, No. 1, pp. 26-35 (1982)
JJ	"In Vitro Production of CFU-S and Cells with Erythropoiesis Repopulating Ability by 5-Fluorouracil Treated Mouse Bone Marrow"; Hodgson, G.S., Bradley, T.R. & Radley, J.M., International Journal of Cell Cloning 1, pp. 49-56 (1983)
KK	"Monoterpenes As Regulators Of Malignant Cell Proliferation"; Hohl, Raymond J., Adv. Exp. Med. Biol., Vol. 401, pp. 136-146 (1996)
LL	"The Myelotoxicity of chloramphenicol: <i>in vitro</i> and <i>in vivo</i> studies: I. <i>In vitro</i> effects on cells in culture"; Holt, D.E., et al, Hum. Exp. Toxicol., Vol. 16, pp. 570-576 (1997)
MM	"Colorimetric determination of inhibition of hematopoietic progenitor cells in soft agar"; Horowitz, D. & King, Andrew G., Journal of Immunological Methods 244, pp. 49-58 (2000)
NN	"Erythroid Colony Formation in Cultures of Mouse and Human Bone Marrow: Analysis of the Requirement for Erythropoietin by Gel Filtration and Affinity Chromatography on Agarose-Concanavalin A"; Iscove, N., Sieber, F. & Winterhalter, H., Journal of Cell. Physiology, 83, pp. 309-320 (1974)
OO	"A Miniaturized Agar Culture System for Cloning Human Erythropoietic Progenitor Cells"; Konwalinka, G., et al, Experimental Hematology, Vol. 12, pp. 75-79 (1984)
PP	"Use of the Microculture Kinetic Assay of Apoptosis to Determine Chemosensitivities of Leukemias"; Kravtsov, V.D., et al, Blood, Vol. 92, No. 3, pp. 968-980 (1998)
QQ	"Chrono Biological Aspects Of Bone Marrow And Blood Cells"; Laerum, O.D. & Aardal, N.P., 11 th Int'l Congress of Anatomy: Biological Rhythms in Structure and Function, pp. 87-97 (1981)
RR	"Hematopoiesis occurs in rhythms"; Laerum, O.D., Experimental Hematology 23, pp. 1145-47 (1995)
SS	" <i>In Vitro</i> Toxicity of A 3'-Azido-3'-Deoxythymidine and Hydroxyurea Combination on Normal Myeloid Progenitors"; Lerza, R., et al, Anticancer Research 18, pp. 2755-58 (1998)
TT	"Improved Plasma Culture System for Production of Erythrocytic Colonies In Vitro: Quantitative Assay Method for CFU-E"; McLeod, D.L., et al, Blood, Vol. 44, No. 4, pp. 517-534 (1974)
UU	"Rapid Colorimetric Assay for Cellular Growth and Survival: Application to Proliferation and Cytotoxicity Assays"; Mosman, Tim, Journal of Immunological Methods, Vol 65, pp. 55-63 (1983)

VV	"A sensitive sandwich ELISA for measuring erythropoietin in human serum"; Noe, G., et al, British Journal of Haematology, Vol. 80, pp. 285-292 (1992)
WW	"Roles for In Vitro Myelotoxicity Tests in Preclinical Drug Development and Clinical Trial Planning"; Parchment, R.E., et al, Toxicologic Pathology, Vol. 21, No. 2, pp. 241-50 (1993)
XX	"Predicting hematological toxicity (myelosuppression) of cytotoxic drug therapy from <i>in vitro</i> tests"; Parchment, R.E., et al, Ann Oncol., Vol. 9, pp. 357-364 (1998)
YY	"In vitro Study of Pesticide Hematotoxicity in Human and Rat Progenitors"; Parent-Massin, D. & Thouvenot, D., Journal of Pharmacological and Toxicological Methods, Vol. 30, pp. 203-207 (1993)
ZZ	"Use of Limiting-Dilution Type Long-Term Marrow Cultures in Frequency Analysis of Marrow-Repopulating and Spleen Colony-forming Hematopoietic Stem Cells in the Mouse"; Ploemacher, R.E., et al, Blood, Vol. 78, No. 10, pp. 2527-2533 (1991)
AAA	"The Induction of Clones of Normal Mast Cells By A Substance From Conditioned Medium"; Pluznik, D.H. & Sachs, L., Experimental Cell Research, Vol. 43, pp. 553-63 (1966)
BBB	"The Effect of Stem Cell Proliferation Regulators Demonstrated With an in vitro Assay"; Pragnell, I.B., et al, Blood, Vol. 72, No. 1, pp. 196-201 (1988)
CCC	"ECVAM's in-house prevalidation/validation studies in the areas of haematotoxicity, reproductive toxicity, metabolism-mediated toxicity and epithelial barrier function"; Prieto, Pilar, The Sciences of the Total Environment, Vol. 247, pp. 349-354 (2000)
DDD	"The Effect of 5-Fluorouracil on Erythropoiesis"; Rich, Ivan, Blood, Vol. 77, No. 6, pp. 1164-70 (1991)
EEE	"The Developmental Biology of Hemopoiesis: Effect of Growth Factors on the Colony Formation by Embryonic Cells"; Rich, Ivan, Experimental Hematology, Vol. 20, pp. 368-70 (1992)
FFF	"Specific Enhancement of Mouse CFU-E by Mouse Transferrin"; Rich, Ivan, et al, British Journal of Haematology, Vol. 49, pp. 567-573 (1981)
GGG	"The effect of reduced oxygen tension on colony formation of erythropoietic cells <i>in vitro</i> "; Rich, Ivan, & Kubanek, B., British Journal of Haematology, Vol. 52, pp. 579-588 (1982)
HHH	"Haemopoietic stem cells are organized for use on the basis of their generation-age"; Rosendaal, M., et al, Nature, Vol. 264, pp. 68-69 (1976)
III	"Circadian Variation in Cell Division of the Mouse Alimentary Tract, Bone Marrow and Corneal Epithelium"; Scheving, L., et al, Anat. Rec., Vol. 191, pp. 479-486 (1978)
JJJ	"The Toxicology of Benzene"; Synder, Robert., et al, Environmental Health Perspectives, Vol. 100, pp. 293-306 (1993)
KKK	"What controls hair follicle cycling?"; Stenn, K.S., et al, Experimental Dermatology, Vol. 8, pp. 229-236 (1999)
LLL	"Distinct circadian time structures characterize myeloid and erythroid progenitor and multipotential cell clonogenicity as well as marrow precursor proliferation dynamics"; Wood, Patricia, et al, Experimental Hematology, Vol 26, pp. 523-533 (1998)

	MMM	"Expression of the Circadian Clock Genes <i>clock</i> and <i>period1</i> in Human Skin"; Zanello, Susana, et al, Journal of Invest Dermatol., Vol. 115, pp. 757-760 (2000)
	NNN	"The sensitivity of in vitro erythropoietic progenitor cells to different erythropoietin reagents during development and the role of cell death in culture"; Zimmerman, Frank & Rich, Ivan, Experimental Hematology, Vol. 24, pp. 330-39 (1996)